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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

AT 8:30____M WILLIAM T. WALSH CLERK

SMITHKLINE BEECHAM CORP. d/b/a GLAXOSMITHKLINE,

Plaintiff,

٧.

RANBAXY LABORATORIES, LTD. and RANBAXY PHARMACEUTICALS INC.

Defendants.

Civil Action No 03CV2158 (MLC)

Hon. Mary Little Cooper

STIPULATION AND [PROPOSED]
ORDER

Plaintiffs SmithKline Beecham Corp. d/b/a GlaxoSmithKline ("Plaintiff") and defendant Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals Inc. ("Defendants") (collectively, "the Parties") hereby stipulate by and through their respective attorneys that all claims, counterclaims and defense in the above-entitled action ("the Litigation") are dismissed with prejudice pursuant to Rules 41(a) and 41(c) of the Federal Rules of Civil Procedure without costs or attorneys' fee to either party. In support thereof, the Parties now stipulate as follows:

- In the above captioned action, Plaintiff raised claims having a reasonable basis in law and
 fact regarding whether Defendants infringed the '924 Patent by Defendants' submission
 of Abbreviated New Drug Application Number 76-588 (Defendants' ANDA) to the
 United States Food and Drug Administration ("FDA").
- Defendants' ANDA was submitted to the FDA under 21 U.S.C. §355(j), and sought FDA
 approval for certain drug products containing as their active ingredient the compound
 valacyclovir hydrochloride ("Valacyclovir"). Defendants' ANDA was approved on
 January 31, 2007.

- 3. In addition, Defendants' ANDA contains a Paragraph IV certification against Plaintiff's U.S. Patent No. 5,879,706 and U.S. Patent No. 6,107,302 (together, the "Additional Patents") related to Plainitiff's Valtrex (Valacyclovir HCL) oral tablet products. Under these Additional Patents, there is a risk of future litigation both Parties seek to avoid as part of this settlement.
- 4. Plaintiff and Defendant have reached an agreement to settle the Litigation and to avoid possible litigation regarding the Additional Patents, which is set forth in this Stipulation and Order of Dismissal and a separate Settlement Agreement. As a result of this settlement, there will be an opportunity for procompetitive generic competition for Valacyclovir oral tablets for human use without risk that such products will subsequently be deemed to violate the '924 Patent or the Additional Patents and be withdrawn from the market. This competition otherwise may not have existed until the expiration of Plaintiff's '924 patent (and its associated pediatric exclusivity) and the expiration of the Additional Patents on [], 2016 and [], 2016 respectively. The settlement allows generic entry of Valacyclovir oral tablets for human use in advance of the expiration of Plaintiffs' '924 patent and its associated pediatric exclusivity and in advance of the expiration of Plaintiffs' Additional Patents.
- 5. This Stipulated Order and the Settlement Agreement are the only consideration exchanged between the Parties in reaching the agreement to settle the Litigation. Plaintiff and Defendant have received no consideration for their entry into this settlement other than that described in these documents. This settlement constitutes Defendant's best independent judgment as to how most expeditiously and competitively to resolve the legitimate issues raised in this proceeding and to avoid the possibility of litigation related

- to the Additional Patents and to sell generic Valacyclovir oral tablets in the United States in light of Defendants' relative chances of success in the Litigation and the relative risks associated with possible future litigation.
- 6. The Parties have each submitted the Settlement Agreement to the U.S. Federal Trade Commission ("FTC") and U.S. Department of Justice (the "DOJ") pursuant to Section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003. Pursuant to paragraph 4(b) of the Settlement Agreement, there has been no Negative Response to the provisions of this agreement from either the FTC (or its staff) or the DOJ.
- 7. Each party to this Litigation will bear its own costs and attorneys' fees.
- 8. Plaintiff and Defendant each consent to personal jurisdiction in the State of New Jersey for purposes of enforcing the Settlement Agreement. The Court shall retain jurisdiction over any matters related to or arising from the interpretation or enforcement of the Settlement Agreement.

| SO STIPULATED: | SMITHKLINE BEECHAM CORP. d/b/a GLAXOSMITHKLINE |
|---|---|
| Date: July 23, 2007 | By: Agley (. Ca) |
| ū | Name: STEPHEN R. LAND |
| | Title: Attorney For Glasswith Hine |
| Date: July 23 2007 | RANBAXY LABORATORIES, LTD. and RANBAXY PHARMACEUTICALS INC. By: |
| ľ | Name: Robert G Shepherd |
| | Pharmacentical Inc. |
| | Ranbard Pharmacentinh Inc. |
| IT IS SO ORDERED. | |
| This # day of \(\frac{\int \pi/\pi}{\pi} \), 2007. | |
| | Hon. Mary Little Cooper U.S. District Judge |